

California Regulatory Notice Register

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The California Regulatory Notice Register is an official state publication of the Office of Administrative Law containing notices of proposed regulatory actions by state regulatory agencies to adopt, amend or repeal regulations contained in the California Code of Regulations. The effective period of a notice of proposed regulatory action by a state agency in the California Regulatory Notice Register shall not exceed one year [Government Code § 11346.4(b)]. It is suggested, therefore, that issues of the California Regulatory Notice Register be retained for a minimum of 18 months.

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PROPOSED ACTION ON REGULATIONS

Information contained in this document is published as received from agencies and is not edited by Thomson West.

TITLE 5. BOARD OF EDUCATION

NOTICE OF PROPOSED RULEMAKING AMENDMENT TO TITLE 5, CALIFORNIA CODE OF REGULATIONS REGARDING ALTERNATIVE SCHOOLS ACCOUNTABILITY MODEL PRE-POST ASSESSMENTS

[Notice published March 17, 2006]

NOTICE IS HEREBY GIVEN that the State Board of Education (State Board) proposes to adopt the regulations described below after considering all comments, objections, or recommendations regarding the proposed action.

PUBLIC HEARING

California Department of Education staff, on behalf of the State Board, will hold a public hearing beginning at **1:00 p.m. on May 3, 2006**, at 1430 N Street, Room 4101, Sacramento. The room is wheelchair accessible. At the hearing, any person may present statements or arguments, orally or in writing, relevant to the proposed action described in the Informative Digest. The State Board requests that any person desiring to present statements or arguments orally notify the Regulations Coordinator of such intent. The State Board requests, but does not require, that persons who make oral comments at the hearing also submit a written summary of their statements. No oral statements will be accepted subsequent to this public hearing.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to:

Debra Strain, Regulations Coordinator LEGAL DIVISION California Department of Education 1430 N Street, Room 5319 Sacramento, California 95814 Comments may also be submitted by facsimile (FAX) at (916) 319–0155 or by e-mail to <u>regulations@cde.ca.gov</u>. Comments must be received by the Regulations Coordinator prior to **5:00 p.m. on May 3, 2006**

AVAILABILITY OF CHANGED OR MODIFIED TEXT

Following the public hearing and considering all timely and relevant comments received, the State Board may adopt the proposed regulations substantially as described in this Notice or may modify the proposed regulations if the modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified regulation will be available for 15 days prior to its adoption from the Regulations Coordinator and will be mailed to those persons who submit written comments related to this regulation, or who provide oral testimony if a public hearing is held, or who have requested notification of any changes to the proposal.

AUTHORITY AND REFERENCE

Authority: Section 33031, Education Code. Reference Section 52052, Education Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Senate Bill 1x (SB 1x), the Public Schools Accountability Act (PSAA), Chapter 3 of the Statutes of 1999, added Chapter 6.1 (commencing with section 52050) to the Education Code (EC). EC section 52052 (g) requires that "by...July 1, 2000, the State Superintendent of Public Instruction, with the approval of the State Board of Education, shall develop an alternative accountability system for schools with fewer than 100 pupils, and for schools under the jurisdiction of a county board of education or a county superintendent of schools, community day schools, and alternative schools, including continuation high schools and independent study schools."

The State Board of Education adopted 5 CCR sections 1068–1074 to develop the alternative accountability system required under SB 1x. As part of that adoption, section 1074, Reporting, was implemented stating that the "District shall submit the ASAM pre–post assessment instrument results to CDE or its designee by July 31 each year." This requires that each school participating in the Alternative Schools Accountability Model (ASAM) that selects a pre–post indicator (Indicators of Achievement: 8, Writing; 9, Reading; and 10, Mathematics) to log on to WestEd's Pre–Post Assess-

ment Tracking and Reporting System (PATRS) to report pre–post assessment indicator data by July 31 and to log on to CDE's ASAM Online Reporting System to report performance indicator (Performance Indicators: 1–6 and 11–15) data.

DISCLOSURES REGARDING THE PROPOSED REGULATION

The State Board has made the following initial determinations:

Mandate on local agencies or school districts: None Cost or savings to state agencies: None

Costs to any local agencies or school districts for which reimbursement would be required pursuant to Part 7 (commencing with section 17500) of division 4 of the Government Code: None

Other non-discretionary cost or savings imposed on local educational agencies: None

Cost or savings in federal funding to the state: None Significant, statewide adverse economic impact directly affecting business including the ability of California businesses to compete with businesses in other states: None

Cost impacts on a representative private person or businesses: The State Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Adoption of these regulations will not 1) create or eliminate jobs within California; 2) create new businesses or eliminate existing businesses within California, or 3) affect the expansion of businesses currently doing business within California.

Effect on housing costs: None

Effect on small businesses: The proposed regulations would not have a significant adverse economic impact on any business because they relate only to county offices of education and not to small business practices.

CONSIDERATION OF ALTERNATIVES

The State Board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the State Board, would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action.

The State Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Inquiries concerning the content of this regulation may be directed to:

Robert Bakke, Education Programs Consultant Educational Options Office California Department of Education 1430 N Street, Room 4503 Sacramento, CA 95814 Telephone: (916) 322–5012

Inquiries concerning the regulations process may be directed to the Regulations Coordinator or Connie Diaz, Regulations Analyst, at (916) 319–0860.

INITIAL STATEMENT OF REASONS AND INFORMATION

The State Board has prepared an initial statement of reasons for the proposed regulation and has available all the information upon which the proposal is based.

TEXT OF PROPOSED REGULATION AND CORRESPONDING DOCUMENTS

Copies of the exact language of the proposed regulation and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Regulations Coordinator. These documents may also be viewed and downloaded from the Department of Education's web site at http://www.cde.ca.gov/re/lr/rr.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the Regulations Coordinator.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the Regulations Coordinator.

REASONABLE ACCOMMODATION FOR ANY INDIVIDUAL WITH A DISABILITY

Pursuant to the *Rehabilitation Act of 1973*, the *Americans with Disabilities Act of 1990*, and the *Unruh Civil Rights Act*, any individual with a disability who requires reasonable accommodation to attend or participate in a public hearing on proposed regulations, may request assistance by contacting Robert Bakke, Education Options Office, 1430 N Street, Sacramento, CA, 95814;

telephone, (916) 322–5012; fax, (916) 323–2039. It is recommended that assistance be requested at least two weeks prior to the hearing.

TITLE 5. BOARD OF EDUCATION

NOTICE OF PROPOSED RULEMAKING AMENDMENT TO TITLE 5, CALIFORNIA CODE OF REGULATIONS REGARDING FOOD SALES, FOOD SERVICE, NUTRITION EDUCATION, AND THE CALIFORNIA FRESH START PILOT PROGRAM

[Notice published March 17, 2006]

NOTICE IS HEREBY GIVEN that the State Board of Education (State Board) proposes to adopt the regulations described below after considering all comments, objections, or recommendations regarding the proposed action.

PUBLIC HEARING

California Department of Education staff, on behalf of the State Board, will hold a public hearing beginning at **10:00 a.m. on May 2, 2006**, at 1430 N Street, Room 1101, Sacramento. The room is wheelchair accessible. At the hearing, any person may present statements or arguments, orally or in writing, relevant to the proposed action described in the Informative Digest. The State Board requests that any person desiring to present statements or arguments orally notify the Regulations Coordinator of such intent. The State Board requests, but does not require, that persons who make oral comments at the hearing also submit a written summary of their statements. No oral statements will be accepted subsequent to this public hearing.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to:

Debra Strain, Regulations Coordinator LEGAL DIVISION California Department of Education 1430 N Street, Room 5319 Sacramento, California 95814

Comments may also be submitted by facsimile (FAX) at (916) 319–0155 or by e-mail to regulations@cde.ca.gov. Comments must be received by the Regulations Coordinator prior to **5:00 p.m. on** May **2, 2006**.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

Following the public hearing and considering all timely and relevant comments received, the State Board may adopt the proposed regulations substantially as described in this Notice or may modify the proposed regulations if the modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified regulation will be available for 15 days prior to its adoption from the Regulations Coordinator and will be mailed to those persons who submit written comments related to this regulation, or who provide oral testimony if a public hearing is held, or who have requested notification of any changes to the proposal.

AUTHORITY AND REFERENCE

Authority: Section 33031 and 49565.8, Education Code.

Reference: Sections 8482.3, 38080, 49434, 49565, 49565.1, 49565.2, 49565.3, 49565.4, 49565.5, 49565.6, 49565.8, Education Code; Title 7 CFR Parts 210 and 220; Child Nutrition and WIC Reauthorization Act of 2004, P.L. 108–265; Child Nutrition Act of 1966 as amended by P.L. 108–265.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

SB 81 requires the California Department of Education to administer the California Fresh Start (CFS) Pilot Program in consultation with the California Department of Food and Agriculture and the Department of Health Services to encourage public schools to provide fruits and vegetables to pupils with priority given to fresh fruits and vegetables from California producers.

The purpose of these regulations is to facilitate implementation of SB 281 by providing clear, consistent procedures for the CFS Pilot Program.

INCORPORATION BY REFERENCE

The United States Department of Agriculture *Food Buying Guide for Child Nutrition Programs (Guide)*, 2005 edition, is incorporated by reference because it would be cumbersome and impractical to publish it in the regulations. The Guide is available via the Regulations Coordinator.

DISCLOSURES REGARDING THE PROPOSED REGULATION

The State Board has made the following initial determinations:

Mandate on local agencies or school districts: None.

Cost or savings to state agencies: None.

Costs to any local agencies or school districts for which reimbursement would be required pursuant to Part 7 (commencing with section 17500) of division 4 of the Government Code: None.

Other non-discretionary cost or savings imposed on local educational agencies: None.

Cost or savings in federal funding to the state: None.

Significant, statewide adverse economic impact directly affecting business including the ability of California businesses to compete with businesses in other states; None.

Cost impacts on a representative private person or businesses: The State Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Adoption of these regulations may 1) create or eliminate jobs within California; 2) create new businesses within California; or 3) cause the expansion of businesses currently doing business within California.

Effect on housing costs: None.

Effect on small businesses: The proposed regulations would not have a significant adverse economic impact on any business because they relate only to school districts and not to small business practices.

CONSIDERATION OF ALTERNATIVES

The State Board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the State Board, would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action.

The State Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Inquiries concerning the content of this regulation may be directed to:

Phyllis Bramson–Paul, Director Nutrition Services Division California Department of Education 560 J Street, Room 270 Sacramento, CA 95814 Telephone: (916) 445–0850

INITIAL STATEMENT OF REASONS AND INFORMATION

The State Board has prepared an initial statement of reasons for the proposed regulation and has available all the information upon which the regulation is based.

TEXT OF PROPOSED REGULATION AND CORRESPONDING DOCUMENTS

Copies of the exact language of the proposed regulation and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Regulations Coordinator. These documents may also be viewed and downloaded from the Department of Education's web site at http://www.cde.ca.gov/re/lr/rr.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the Regulations Coordinator.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the Regulations Coordinator.

REASONABLE ACCOMMODATION FOR ANY INDIVIDUAL WITH A DISABILITY

Pursuant to the *Rehabilitation Act of 1973*, the *Americans with Disabilities Act of 1990*, and the *Unruh Civil Rights Act*, any individual with a disability who requires reasonable accommodation to attend or participate in a public hearing on proposed regulations, may request assistance by contacting Angie Avila, Nutrition Services Division, 560 J Street, Sacramento, CA, 95814; telephone, (916) 323–0122; fax, (916) 327–6667. It is recommended that assistance be requested at least two weeks prior to the hearing.

TITLE 5. BOARD OF EDUCATION

NOTICE OF PROPOSED RULEMAKING AMENDMENT TO TITLE 5, CALIFORNIA CODE OF REGULATIONS REGARDING CALIFORNIA HIGH SCHOOL EXIT EXAMINATION (CAHSEE)

[Notice published March 17, 2006]

NOTICE IS HEREBY GIVEN that the State Board of Education (State Board) proposes to adopt the regu-

lations described below after considering all comments, objections, or recommendations regarding the proposed action.

PUBLIC HEARING

California Department of Education staff, on behalf of the State Board, will hold a public hearing beginning at **1:00 p.m. on May 3, 2006**, at 1430 N Street, Room 1101, Sacramento. The room is wheelchair accessible. At the hearing, any person may present statements or arguments, orally or in writing, relevant to the proposed action described in the Informative Digest. The State Board requests that any person desiring to present statements or arguments orally notify the Regulations Coordinator of such intent. The State Board requests, but does not require, that persons who make oral comments at the hearing also submit a written summary of their statements. No oral statements will be accepted subsequent to this public hearing.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to:

Debra Strain, Regulations Coordinator LEGAL DIVISION California Department of Education 1430 N Street, Room 5319 Sacramento, California 95814

Comments may also be submitted by facsimile (FAX) at (916) 319–0155 or by e-mail to regulations@cde.ca.gov. Comments must be received by the Regulations Coordinator prior to **5:00 p.m. on May 3, 2006**.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

Following the public hearing and considering all timely and relevant comments received, the State Board may adopt the proposed regulations substantially as described in this Notice or may modify the proposed regulations if the modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified regulation will be available for 15 days prior to its adoption from the Regulations Coordinator and will be mailed to those persons who submit written comments related to this regulation, or who provide oral testimony if a public hearing is held, or who have requested notification of any changes to the proposal.

AUTHORITY AND REFERENCE

Authority: Section 33031, Education Code. Reference: Sections 37252, 60851 and 60852.3, Education Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Currently, the title 5 regulations for the California High School Exit Examination (CAHSEE) provide adult students with two opportunities per year to take the portion(s) of the CAHSEE not yet passed. The California Department of Education has received feedback from the adult education community that many adult students are in circumstances (e.g., seeking employment, applying for the military) that present an urgent need to obtain a high school diploma. The proposed regulations will assist adult students in meeting this need by providing them with one additional opportunity per year to take the portion(s) of the CAHSEE not yet passed and eliminating the prohibition from testing in successive administrations, beginning in the 2006-07 school year (July 1, 2006-June 30, 2007). Emergency regulations are proposed to provide school districts with sufficient time to plan or modify their CAHSEE administration schedules to incorporate an additional opportunity for adult students.

Existing law provides a one—year exemption of the requirement to pass the CAHSEE for students with disabilities in the class of 2006 who satisfy certain requirements. This new law, which took effect immediately, also requires school districts to report to the State Board of Education and the State Superintendent of Public Instruction information pertaining to students with disabilities. The proposed regulations will implement the statutory data reporting requirements pursuant to Education Code sections 60851 and 60852.3.

DISCLOSURES REGARDING THE PROPOSED REGULATION

The State Board has made the following initial determinations:

Mandate on local agencies or school districts: None. Cost or savings to state agencies: None.

Costs to any local agencies or school districts for which reimbursement would be required pursuant to Part 7 (commencing with section 17500) of division 4 of the Government Code: None.

Other non-discretionary cost or savings imposed on local educational agencies: None.

Cost or savings in federal funding to the state: None.

Significant, statewide adverse economic impact directly affecting business including the ability of

California businesses to compete with businesses in other states: None.

Cost impacts on a representative private person or businesses: The State Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Adoption of these regulations will not 1) create or eliminate jobs within California; 2) create new businesses or eliminate existing businesses within California; or 3) affect the expansion of businesses currently doing business within California.

Effect on housing costs: None.

Effect on small businesses: The proposed regulations would not have a significant adverse economic impact on any business because they relate only to county offices of education and not to small business practices.

CONSIDERATION OF ALTERNATIVES

The State Board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the State Board, would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action.

The State Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Inquiries concerning the content of this regulation may be directed to:

Jessica Valdez, Education Programs Consultant High School Exit Exam Office California Department of Education 1430 N Street, Room 5408 Sacramento, CA 95814 Telephone: (916) 319–0354

Inquiries concerning the regulations process may be directed to the Regulations Coordinator or Connie Diaz, Regulations Analyst, at (916) 319–0860.

INITIAL STATEMENT OF REASONS AND INFORMATION

The State Board has prepared an initial statement of reasons for the proposed regulation and has available all the information upon which the proposal is based.

TEXT OF PROPOSED REGULATION AND CORRESPONDING DOCUMENTS

Copies of the exact language of the proposed regulation and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Regulations Coordinator. These documents may also be viewed and downloaded from the Department of Education's web site at http://www.cde.ca.gov/re/lr/rr.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the Regulations Coordinator.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the Regulations Coordinator.

REASONABLE ACCOMMODATION FOR ANY INDIVIDUAL WITH A DISABILITY

Pursuant to the *Rehabilitation Act of 1973*, the *Americans with Disabilities Act of 1990*, and the *Unruh Civil Rights Act*, any individual with a disability who requires reasonable accommodation to attend or participate in a public hearing on proposed regulations, may request assistance by contacting Jessica Valdez, High School Exit Exam Office, 1430 N Street, Sacramento, CA, 95814; telephone, (916) 319–0354; fax, (916) 319–0967. It is recommended that assistance be requested at least two weeks prior to the hearing.

TITLE 16. BOARD OF PSYCHOLOGY

DEPARTMENT OF CONSUMER AFFAIRS

NOTICE IS HEREBY GIVEN that the Board of Psychology (hereinafter "board") is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the Hilton Los Angeles Airport Hotel, 5711 West Century Boulevard, Los Angeles, California, at 9:00 a.m., or as soon as practicable thereafter, on May 6, 2006. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the board at its office not later than 5:00 p.m. on Wednesday, May 3, 2006, or must be received by the board at the hearing. The board, upon its own motion or

at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Section 2930 of the Business and Professions Code, and to implement, interpret or make specific Sections 2960, 2960.05, 2960.1, 2960.5, 2960.6, 2961, 2962, 2963, 2964, 2964.3, 2964.5, 2964.6, 2965, 2966, 2969, Business and Professions Code, and Section 11425.50(e) of the Government Code, the board is considering changes to Division 13.1 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Government Code Section 11425.50(e) provides that a penalty in an administrative disciplinary action may not be based on a guideline unless the guideline has been adopted as a regulation. To conform to this requirement, the board previously adopted "Disciplinary Guidelines as amended 9/1/02," which set forth proposed penalties for various violations of the Psychology License Law.

This proposal would incorporate by reference the Disciplinary Guidelines as amended by the board on 2/4/06.

FISCAL IMPACT ESTIMATES

<u>Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal</u> Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

<u>Impact on Jobs/New Businesses</u>:

The board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

<u>Cost Impact on Representative Private Person or</u> Business:

The board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The board has determined that the proposed regulations would affect small businesses.

CONSIDERATION OF ALTERNATIVES

The board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above—mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The board has prepared an initial statement of reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Psychology at 1422 Howe Avenue, Suite 22, Sacramento, California 95825

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which

is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Kathy Bradbury

Address: 1422 Howe Avenue, Suite 22

Sacramento, CA 95825

Telephone No.: (916) 263–0712 Fax No.: (916) 263–2697

E-Mail Address: kathy_bradbury@dca.ca.gov

The backup contact person is:

Name: Jeffrey Thomas

Address: 1422 Howe Avenue, Suite 22

Sacramento, CA 95825

Telephone No.: (916) 263–1617 Fax No.: (916) 263–2697

E-Mail Address: jeff_thomas@dca.ca.gov

<u>Website Access</u>: Materials regarding this proposal can be found at www.psychboard.ca.gov.

TITLE 16. BOARD OF PSYCHOLOGY

NOTICE IS HEREBY GIVEN that the Board of Psychology (hereinafter "board") is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the Hilton Los Angeles Airport Hotel, 5711 West Century Boulevard, Los Angeles, California, at 9:00 a.m., or as soon as practicable thereafter, on May 6, 2006. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the board at its office not later than 5:00 p.m. on Wednesday, May 3, 2006 or must be received by the board at the hearing. The board, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

<u>Authority and Reference</u>: Pursuant to the authority vested by Sections 2914 and 2930 of the Business and Professions Code, and to implement, interpret or make specific Section 2914 of said Code, the board is considering changes to Division 13.1 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Currently, existing section 1387(a)(2) allows applicants for licensure as a psychologist to accrue postdoctoral supervised professional experience (SPE) as follows:

As a registered psychologist pursuant to section 2909(d) of the code and registration with the board prior to commencing work is required; or

As an employee of an exempt setting pursuant to section 2910 of the code and registration with the board is not required; or

As a psychological assistant pursuant to section 2913 of the code and registration with the board prior to commencing work is required; or

Pursuant to a Department of Mental Health Waiver (5751.2 Welfare and Institutions Code) for which registration with the board is not required.

Pursuant to SB 229, Chapter 658, Statutes of 2005, this proposal would add the following acceptable post-doctoral supervised professional experience:

In a formal postdoctoral internship overseen by the American Psychological Association (APA), the Association of Psychology Postdoctoral and Internship Centers (APPIC), or the California Psychology Internship Council (CAPIC) pursuant to section 2911 of the code and registration with the board is not required.

The definition of "formal internship" is being relocated under 1387(a)(1)(A) to be consistent with the predoctoral supervised professional experience.

Currently, section 1387(b)(9) states that "SPE gained while the trainee is functioning under another mental health license or credential, shall not be credited toward meeting the requirements for the psychologist's license." As it is currently written, this regulation disallows SPE hours accrued at a public school by a person working as a school psychologist since school psychologists are required by California law to have a pupil personnel services credential through the Commission on Teacher Credentialing. Therefore, this proposal would eliminate the words "or credential" in order to accept hours of SPE accrued at a public school by a person working as a school psychologist.

Currently, section 1390.3 states that a person meeting the requirements set forth in Business and Professions Code section 2909(d), may provide psychological services under supervision at a non–profit community agency that receives at least 25 percent of its funding from a governmental source for the purpose of training and providing services so long as that person registers with the board as a registered psychologist. Currently, the registration is valid for two years. This proposal would extend the registration to 30 months from the date of registration as amended in section 2909(d) of the Business and Professions Code pursuant to SB 229, Chapter 658, Statutes of 2005.

FISCAL IMPACT ESTIMATES

Fiscal impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

AND

The following studies/relevant data were relied upon in making the above determination:

Senate Bill 229, Chapter 685, Statutes of 2005 Impact on Jobs/New Businesses:

The board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

<u>Cost Impact on Representative Private Person or Business:</u>

The board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The board has determined that the proposed regulation would affect small businesses.

CONSIDERATION OF ALTERNATIVES

The board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above—mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Psychology at 1422 Howe Avenue, Suite 22, Sacramento, California 95825.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Kathy Bradbury

Address: 1422 Howe Avenue, Suite 22

Sacramento, CA 95825

Telephone No.: (916) 263–0712 Fax No.: (916) 263–2697

E-Mail Address: kathy_bradbury@dca.ca.gov

The backup contact person is:

Name: Jeffrey Thomas

Address: 1422 Howe Avenue, Suite 22

Sacramento, CA 95825

Telephone No.: (916) 263–1617 Fax No.: (916) 263–2697

E-Mail Address: jeff_thomas@dca.ca.gov

<u>Website Access</u>: Materials regarding this proposal can be found at <u>www.psychboard.ca.gov</u>.

TITLE 16. BOARD OF PSYCHOLOGY

NOTICE IS HEREBY GIVEN that the Board of Psychology (hereinafter "board") is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the Hilton Los Angeles Airport Hotel, 5711 West Century Boulevard, Los Angeles, California, at 9:00 a.m., or as soon as practicable thereafter, on May 6, 2006. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the board at its office not later than 5:00 p.m. on Wednesday, May 3, 2006 or must be received by the board at the hearing. The board, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 2930 and 2946 of the Business and Professions Code, and to implement, interpret or make specific sections 2940, 2946 and 2983 of said Code, the board is considering changes to Division 13.1 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 2946 states that the board, at its discretion, may waive the examinations for applicants who have demonstrated competence in the areas covered by the examinations, including for diplomates of the American Board of Professional Psychology (ABPP). Current regulations waive the national written Examination for Professional Prac-

tice in Psychology (EPPP) for applicants who hold a Certificate of Professional Qualification (CPQ) issued by the Association of State and Provincial Psychology Boards (ASPPB), and applicants who are credentialed as a Health Service Provider in Psychology by the National Register of Health Service Providers in Psychology (NRHSPP). These applicants are deemed to have met the educational and experience requirements of subdivisions (b) and (c) of Code section 2914 and are required to file a complete application and meet all current licensing requirements not addressed above including payment of any fees, and successful completion of the California Psychology Supplemental Examination (CPSE).

This proposal would also waive the EPPP for an applicant who is currently certified by the American Board of Professional Psychology (ABPP) and has been licensed based on a doctoral degree in another state, Canadian province, or U.S. territory for a minimum of five years. Such an applicant shall be deemed to have met the educational and experience requirements of subdivisions (b) and (c) of Code section 2914. Such applicants would also be required to take and pass the CPSE, file a complete application and meet all current licensing requirements not addressed above, including payment of any fees.

This proposal would also amend section 1381.5 to reflect the changes made in section 1388.6 subsection (e) which is being re–lettered to (f) as referenced in section 1381.5.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

<u>Cost Impact on Representative Private Person or</u> Business:

The board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The board has determined that the proposed regulations would affect small businesses.

CONSIDERATION OF ALTERNATIVES

The board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above—mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Psychology at 1422 Howe Avenue, Suite 22, Sacramento, California 95825

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Kathy Bradbury

Address: 1422 Howe Avenue, Suite 22

Sacramento, CA, 95825

Telephone No.: (916) 263–0712 Fax No.: (916) 263–2697

E-Mail Address: kathy_bradbury@dca.ca.gov

The backup contact person is:

Name: Jeffrey Thomas

Address: 1422 Howe Avenue, Suite 22

Sacramento, CA 95825

Telephone No.: (916) 263–1617 Fax No.: (916) 263–2697

E-Mail Address: jeff_thomas@dca.ca.gov

<u>Website Access</u>: Materials regarding this proposal can be found at www.psychboard.ca.gov.

TITLE 16. CONTRACTORS STATE LICENSE BOARD

NOTICE OF PROPOSED CHANGES IN THE REGULATIONS

NOTICE IS HEREBY GIVEN that the Contractors State License Board (Board) is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the Contractors State License Board, 9821 Business Park Drive, Sacramento, California 95827, at 10:00 a.m. on May 2, 2006. Written comments must be received by the Board at its office at the above address not later than May 1, 2006 at 5:00 p.m. or at the hearing. The Board, upon its own motion or at the instance of any interested party, may thereafter adopt the proposal substantially as described below or may modify such proposal if such modification is sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in the Notice as the contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the pro-

Authority and Reference Citations

Pursuant to the authority vested by Sections 7008 and 7099.2 of the Business and Professions (B&P) Code, and to implement, interpret, or make specific Sections 7099 and 7099.1 of said Code, the Contractors State Li-

cense Board is considering changes to Division 8 of Title 16 of the California Code of Regulations (CCR) as follows:

INFORMATIVE DIGEST/PLAIN ENGLISH POLICY STATEMENT OVERVIEW

<u>Amend Section 884 — Recommended Assessment of</u> Civil Penalties.

Section 7008 authorizes the Board to adopt rules and regulations, in accordance with the Administrative Procedures Act, that are reasonably necessary to carry out the provisions of the chapter of the B&P Code. Section 7099.2 directs the Board to adopt regulations covering the assessment of civil penalties, with a maximum penalty of \$5,000 for most violations (recently increased from \$2,000), unless otherwise provided by the chapter (e.g., \$15,000 maximum for specified violations). Section 7099 authorizes the Board to issue citations to licensees or applicants. Section 7099.1 directs the Board to adopt regulations covering the formulation of an order of correction, which gives due consideration to the time required to correct and the practical feasibility of correction.

The existing regulation sets forth a range of recommended minimum and maximum civil penalties the Board can assess for violations of the Contractors License Law, at amounts not to exceed \$2,000, except as otherwise provided by the chapter.

This proposal would amend the regulation in order to:

- Designate the unnumbered introductory paragraph and the table of civil penalties as subsection (a);
- Revise the civil penalty amounts contained in the new subsection (a), based on the new \$5,000 statutory limit;
- Renumber existing subsection (a) to (b);
- Revise and designate subsection numbering for the remaining paragraphs as appropriate; and
- Add criteria that the Registrar will take into consideration when determining the amount of assessed civil penalties.

Local Mandate

The proposed regulatory action does not impose a mandate on local agencies or school districts.

Fiscal Impact on Public Agencies/STD 399

The proposed regulatory action will result in costs and/or savings to the Board. However, the proposed regulatory action will not result in costs or savings to any local agency or school district that is required to be reimbursed under Part 7 of Division 4 (commencing with Section 17500 of the Government Code), other

nondiscretionary costs or savings on local agencies, or costs or savings in federal funding to the state.

Cost Impact on Affected Private Persons

The proposed regulatory action impacts licensed contractors and others in violation of specified statutes and imposes civil penalties for citations issued as a result of violations. The cost impact that a representative private person or business may incur in reasonable compliance with the proposed action varies greatly depending on the statute that was violated and the associated civil penalty amount, as well as other relevant criteria that are taken into consideration such as multiple violations, a history of violations, a serious or harmful violation, etc. Under the proposed civil penalties, the cost impact on affected private persons could range from \$100 to \$15,000 per citation.

Housing Costs

The proposed regulatory action will not have a significant effect on housing costs.

Effect on Small Business

The proposed regulatory action may affect small businesses if they are in violation of specified statutes and are assessed a civil penalty for a citation issued as a result of the violation. CSLB does not maintain statistics on the number of small businesses licensed as contractors in the State of California. However, based on national statistics, approximately 98.2 percent of businesses are small businesses. The effect on small businesses would be the same as the effect on private persons as described above.

Contact Person

Inquiries or comments concerning the proposed administrative action may be addressed to:

Contractors State License Board 9821 Business Park Drive Sacramento, CA 95827 Attn: Peter Sugar (916) 255–0614 (916) 255–1395 (FAX) psugar@dca.cslb.ca.gov

The backup contact person is:

Betsy Figueira (916) 255–2798 (916) 25–1395 (FAX) bfigueira@dca.cslb.ca.gov

Inquiries concerning the substance of the proposed regulations may be directed to Peter Sugar at (916) 255–0614.

Comment Period

Written comments must be received by the Board at the Contractors State License Board, 9821 Business Park Drive, Sacramento, CA 95827 not later than May 1, 2006 at 5:00 p.m. or at the hearing to be held in the Board office at 10:00 a.m. on May 2, 2006.

Availability of Modifications

With the exception of technical or grammatical changes, the full text of any modified proposal will be available from the person designated in this notice as contact person for 15 days prior to its adoption and will be mailed to those persons who submit written or oral testimony related to this proposed regulatory action or who have requested notification of any changes to the proposal.

Reference to Text and Initial Statement of Reasons

The Board has prepared a statement of the reasons for the proposed action, which is available to the public upon request. The express terms of the proposed action and all information upon which the proposal is based are available upon request.

Business Impact

The proposed regulatory action will not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states, because it affects only individual licensed contractors and others who are in violation of specified statutes and who are assessed a civil penalty for a citation issued as a result of the violation.

Impact on Jobs/New Businesses

The proposed regulatory action will not affect the creation or elimination of jobs within the State of California, the creation of new businesses or the elimination of existing businesses within the State of California, or the expansion of businesses currently doing business within the State of California, because it affects only individual licensed contractors and others who are in violation of specified statutes and who are assessed a civil penalty for a citation issued as a result of the violation.

Public Hearing

A public hearing will be held at the Contractors State License Board, 9821 Business Park Drive, Sacramento, California 95827, at 10:00 a.m. on May 2, 2006.

Federal Mandate

The proposed regulatory action is not mandated by federal law or is not identical to any previously adopted or amended federal regulation.

Consideration of Alternatives

The Board must determine that no reasonable alternative which it considered or that has otherwise been identified and brought to its attention would be either more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome on affected private persons than the pro-

posed regulatory action. The actual determination must be part of both the Initial and Final Statement of Reasons.

Availability of the Final Statement of Reasons

Interested parties may obtain a copy of the Final Statement of Reasons once it has been prepared by making a written request to the contact person named above.

Website Access

Materials regarding the proposed regulatory action can be found at www.cslb.ca.gov.

Title 17. CALIFORNIA INSTITUTION FOR REGENERATIVE MEDICINE

NOTICE OF PROPOSED REGULATION ADOPTION AND INITIAL STATEMENT OF REASONS

California Code of Regulations
Title 17. — Public Health
Division 4 – California Institute For
Regenerative Medicine
Chapter 2

Date: March 17, 2006

Deadline for Submission of Written Comment:

May 1, 2006 — 5:00 p.m.

Hearing Date: May 1, 2006

Subject Matter of Proposed Regulations: Medical and Ethical Standards Applicable to CIRM-Funded Research and Training

Sections Affected:

The proposed regulations adopt Chapter 2 and sections 100010, 100020, 100030, 100040, 100050, 100060, 100070, 100080, 100090, 100100, 100110, 100120 and 100130 of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and Health and Safety Code section 125290.40, subdivision (j).

Reference: Sections 439.900–439.906, 100237–100239, 24172, 125290.30, 125290.35, 125290.40, 124290.55, 125292.10, subds. (p)(q), 125300, 125315, Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in early 2005 with the passage of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides \$3 billion in funding for stem

cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens' Oversight Committee ("ICOC") is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The Scientific and Medical Accountability Standards Working Group ("Standards Working Group") makes recommendations to the 29-member ICOC that governs the CIRM on scientific, medical and ethical standards pertaining to stem cell research the institute funds. Specifically, California Health and Safety Code section 125290.55 requires the Standards Working Group to: 1) recommend to the ICOC scientific, medical and ethical standards; 2) recommend to the ICOC standards for all medical, socioeconomic, and financial aspects of clinical trials and therapy delivery to patients, including, among others, standards for safe and ethical procedures for obtaining materials and cells for research and clinical efforts for the appropriate treatment of human subjects in medical research consistent with paragraph (2) of subdivision (b) of Section 125290.35, and to ensure compliance with patient privacy laws; 3) recommend to the ICOC modification of the standards described in numbers (1) and (2) as needed; 4) make recommendations to the ICOC on the oversight of funded research to ensure compliance with the standards described in numbers (1) and (2); 5) advise the ICOC, the Scientific and Medical Research Funding Working Group, and the Scientific and Medical Research Facilities Working Group on an on-going basis on relevant ethical and regulatory issues.

After five public meetings and three public sessions to solicit public comments from across the state, the Standards Working Group finalized these draft regulations on January 31, 2006 that were subsequently approved by the ICOC at its public meeting on February 10, 2006.

Under the proposed regulations, CIRM will be the first agency to: legally mandate specialized review by a Stem Cell Research Oversight (SCRO) committee; enhance state and federal policies in the areas of voluntary—informed consent; and ensure that women's reproductive needs are protected and prioritized before the research. These regulations reaffirm the requirements of Proposition 71, namely a ban on human reproductive cloning and a prohibition of payment to egg donors in the state of California.

The draft regulations adopt a broad definition of "covered stem cell lines" to ensure that human stem cells derived from any source are subject to strict ethical standards. The *Guidelines for Human Embryonic Stem Cell Research* ("National Academy of Sciences Guidelines"), a landmark document drafted by a blue ribbon committee of the National Academy of Sciences which was published May 2005, only covered embryonic stem cell lines.

These regulations create a single "gold" standard intended to ensure that all cell lines used by CIRM—funded researchers are derived according to the highest ethical standards. This revised standard has the practical implication of guaranteeing that all cell lines used by CIRM—funded researchers are derived without payment to egg donors.

These regulations require that research institutions ensure that oocyte (egg) donors do not have to pay for any immediate and short–term complications for oocyte retrieval. The National Academies' guidelines fail to address this issue.

These regulations strengthen existing regulations to make clear that it is not acceptable to provide payments for eggs (beyond reimbursement for expenses) used in CIRM–funded research under any circumstances.

These regulations go above and beyond existing state regulations and federal guidelines for assuring that potential egg donors are fully informed of their decision and the nature of the proposed research. Institutional review committees are required to approve a process for determining whether prospective donors have understood the essential aspects of the research, including but not limited to how eggs will be used and the medical risks associated with participation.

The CIRM draft regulations are substantively based on the National Academy of Sciences Guidelines. Two members of the Standards Working Group served on the NAS blue ribbon committee to develop the Guidelines. To date, the Standards Working Group has received and addressed well over thirty public comments.

Technical, Theoretical or Empirical Studies, Reports or Documents:

CIRM relied upon:

- The National Institutes of Health Report on Stem Cells
- 2) The National Academy of Sciences (NAS) Guidelines for Human Embryonic Stem Cell Research, 2005, available at www.nap.edu/catalog/11278.html.
- 3) The National Institutes of Health Grants Policy Statement
- 4) Title 45, Code of Federal Regulations, Part 46 Protection of Human Subjects

5) Public input received at five public meetings conducted by the Standards Working Group of CIRM on: July 6, 2005; August 30, 2005; October 24, 2005; December 1, 2005; and January 30–31, 2006.

Copies of the documents referenced above in numerals 1) through 4) are available on CIRM's website under the "Regulations" link at www.cirm.ca.gov. These documents are also available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Transcripts and meeting minutes of the meetings referenced in numeral 5) are also available on CIRM's website under the "Standards Working Group" link.

Submittal of Comments:

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. **Written comments** must be received no later than 5:00 p.m. on **May 1, 2006**. Comments regarding this proposed action may also be transmitted via e-mail to <u>MEScomments@cirm.ca.gov</u> or by facsimile transmission to (415) 396–9141.

A public hearing has been scheduled for the time and place stated below to receive **oral comments** regarding the proposed regulatory action.

Date: May 1, 2006

Time: 12:00 p.m. to 4:00 p.m.

Place: Elihu Harris State Building

1515 Clay Street, Training Room #11

Oakland, CA

A CIRM representative will preside at the hearing. Persons who wish to speak will be asked to register before the hearing. The registration of speakers will be conducted at the location of the hearing from 11:30a.m. to 12:00 p.m. Any other person who wishes to speak at the hearing will be afforded the opportunity to do so after the registered persons have been heard. If the number of registered persons in attendance warrants, the hearing officer may limit the time for each presentation in order to allow everyone wishing to speak the opportunity to be heard. Oral comments presented at a hearing carry no more weight than written comments.

Effect on Small Business:

CIRM has determined that the proposed regulatory action has no impact on small businesses. The regulations implement conditions on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private non–profit institutions, as well as large for–profit institutions. As such, the regulations are not expected to adversely impact small business as defined in Government Code section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed regulatory action.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory actions.

Effect on Housing Costs:

CIRM has made an initial determination that the proposed actions will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. The CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Impact on the Creation, Elimination, or Expansion of Jobs:

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

Consideration of Alternatives:

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective

and less burdensome to affected private persons or businesses than the regulatory action.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After the close of the comment period, CIRM may make the regulation permanent if it remains substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the regulation, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing; and inquiries regarding the rulemaking file may be directed to:

C. Scott Tocher, Interim Counsel California Institute For Regenerative Medicine 210 King Street San Francisco, CA 94107 (415) 396–9100

Questions on the substance of the proposed regulatory action may be directed to:

Geoff Lomax, Senior Officer for Medical and Ethical Standards California Institute For Regenerative Medicine (415) 396–9134

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact person named above. In addition, the Final

Statement of Reasons will be posted on CIRM's web-page and accessed at www.cirm.ca.gov.

Specific Purpose and Factual Basis for each adoption:

SECTION 100010 — SCOPE

<u>Purpose</u>

Section 100010 establishes the scope of the regulations comprising Chapter 2. The standards contained in this chapter apply to all institutions performing research funded by the agency.

Rationale:

This section is necessary to define the circumstances and extent to which this chapter is to be applied.

SECTION 100020 — DEFINITIONS

Purpose

The following definitions shall apply to language contained in Sections 100010 through I00130 of these regulations.

- (a). "Acceptably Derived." This term defines materials that may be used in CIRM-funded research. The definition refers to the materials and the manner in which they are obtained as defined further in sections 100080 and 100090. Health and Safety Code section 125290.55, subdivision (b)(2), requires CIRM to adopt standards for all medical, socioeconomic, and financial aspects of clinical trials and therapy delivery to patients, including, among others, standards for safe and ethical procedures for obtaining materials and cells for research and clinical efforts for the appropriate treatment of human subjects in medical research consistent with paragraph (2) of subdivision (b) of Section 125290.35, and to ensure compliance with patient privacy laws. This subdivision describes the materials that govern the "obtaining" of those materials.
- **(b). "CIRM."** This acronym stands for the agency created by Proposition 71, adopted by the voters in November, 2004, the California Institute for Regenerative Medicine. This is the agency that has oversight and implementation authority for Proposition 71.
- (c). "Covered Stem Cell Line." CIRM—funded research applies to a broader range of materials including but not limited to adult stem cells, fetal tissue and placenta derived cells. Proposition 71 includes definitions of "adult stem cells," "pluripotent cells," and "stem cells," (Health and Safety Code section 125292.10, subdivisions (b), (q) and (x). Also, Health and Safety Code section 125300, subdivision (a), describes the policy of the State of California involving research using many types of cells under different circumstances. This definition is consistent with the definitions already in Proposition 71 because it incorporates language consistent with the definition of the terms above. The focus on cell lines in culture alleviates concerns that scope of regulation is overly expansive.

- (d). "Funded Research." This term defines "funded research" to mean research conducted with funding provided pursuant to grants issued by CIRM in accordance with Proposition 71. Because CIRM also funds grants used for training scientists in stem—cell research, the term is further defined to include these subjects, as well
- **(e). "Human Subject."** Certain statutes and regulations apply in the context of research conducted on or with human subjects. The definition of "human subject" is derived from the Code of Federal Regulations, Title 45, Part 46, and National Academy of Sciences Guidelines, Number 3.1. This is a definition with which the regulated community is familiar.
- **(f). "Institution."** This term is defined to include any public or private entity or agency, whether state, local or federal. This definition is based on the federal common rule, as embodied in the Code of Federal Regulations, Title 45, Part 46, and National Academy of Sciences Guidelines, Number 3.1. This is a definition with which the regulated community is familiar.
- (g). "Institutional Review Board." Health and Safety Code section 125290.35, subdivision (b)(2), requires CIRM to adopt standards for controls on research involving humans and that these be based in part on "institutional review board" ("IRB") standards. An IRB is an entity established pursuant to federal law that oversees certain federally funded research. Stem cell research conducted on humans with federal funds must be approved by an IRB. This term is defined to mean those boards created pursuant to federal regulation.
- (h). "Permissible Expenses." Health and Safety Code section 125290.35, subdivision (b)(3), prohibits compensation to research donors or participants but allows reimbursement of expenses. "Permissible expenses" means necessary and reasonable costs directly incurred as a result of donation or participation in research activities. Permissible expenses may include but are not limited to costs associated with travel, housing, child care, medical care, health insurance and actual lost wages.
- (i). "Research." These regulations apply to training grants as well as research funded by CIRM. This term based on and consistent with the federal definition, as contained in the Code of Federal Regulations, Title 45, Part 46, and National Academy of Sciences Guidelines, Number 3.1. This definition is therefore one with which the regulated community has experience and is familiar.
- (j.) "Somatic Cell Nuclear Transfer (SCNT)." This term means the transfer of a cell nucleus from a somatic cell into an oocyte from which the nucleus has been removed. This definition is based on that of the National Institutes of Health definition at the federal level and is consistent therewith.

(k). "Stem Cell Research Oversight Committee." This terms means a committee established in accordance with 17 California Code of Regulations, Section 100060. The purpose is to provide oversight of all issues related to derivation and use of human embryonic stem ("hES") cell lines and to facilitate education of investigators involved in hES cell research.

Rationale:

To make specific the language and terminology used in formulating regulations.

<u>SECTION 100030</u> — <u>ACTIVITIES NOT ELIGIBLE</u> FOR CIRM FUNDING:

Purpose:

This section defines research activities not eligible for CIRM funding. They include human reproductive cloning, the in vitro culture of 1) any intact human embryo or 2) any product of SCNT after appearance of the primitive streak or after 12 days, whichever is earlier. The 12–day period does not include time the embryo and/or cells have been stored frozen. Also prohibited are the introduction of stem cells from a covered stem cell line into nonhuman primate embryos, the introduction of stem cells into human embryos, and the breeding of any animal into which stem cells from a covered stem cell line have been introduced. The purpose of these restrictions is to ensure compliance with existing state and federal policy in this area.

Rationale: California Health and Safety Code Sections 125292.10, subdivision (b), and 125290.35, subdivision (b)(6), prohibit human reproductive cloning and a limit on time during which cells may be extracted from blastocysts beyond 8 to 12 days, respectively. The CIRM is charged with adopting standards applicable to the use of cells in research funded by the agency. The remaining provisions of the regulation are direct recommendations of the National Academy of Sciences Guidelines and are considered necessary elements to ensure ethical and appropriate conduct of stem cell research.

<u>SECTION 100040 — INSTITUTIONAL ASSURANCE OF COMPLIANCE</u>:

Purpose:

CIRM is responsible for ensuring grantees comply with the Act and applicable regulations. All research institutions shall be responsible for providing written assurance satisfactory to CIRM that CIRM—funded research complies with the requirements set forth in this chapter. To further ensure that compliance, the regulation specifies that each institution shall 1) designate an institutional official responsible for oversight of and documentation of compliance for CIRM—funded research; 2) designate one or more SCRO committee(s) established in accordance with the requirements of Title

17, California Code of Regulations, Section 100060; 3) designate one or more Institutional Review Boards; and 4) ensure that clinical personnel who have a conscientious objection not be required to participate in providing donor information or securing donor consent for research use of gametes or embryos.

Rationale:

This regulation is necessary to ensure CIRM is able to monitor compliance among recipients with critical state laws and regulations. Health and Safety Code section 125300, subdivision (b), states that research involving the derivation and use of human embryonic stem cells, germ cells, and adult stem cells, in addition to others, shall be reviewed by an approved institutional review board. The remaining provisions embody National Academy Guidelines adopted to guide federally funded research in this area.

The establishment of an SCRO ensures that proposed research is reviewed by an expert panel to ensure the research is permissible and ethical. The SCRO is the best method to ensure proper oversight of all issues related to derivation and use of human embryonic stem cells. These provisions ensure consistency where possible with important federal guidelines and embody common practice in this area.

SECTION 100050 — COMPLIANCE:

Purpose:

This section states that grantees must report promptly to CIRM any failure to comply with the terms and conditions of an award. Depending on the severity and duration of the non–compliance, consequences for failure to comply with the terms and conditions are identified.

Rationale:

This regulation is necessary to ensure that CIRM grantees are under obligation to inform CIRM when there has been a failure of compliance. In light of the fact that research is not conducted by CIRM staff nor is CIRM staff available at the site of research to provide uniform monitoring of all grantee activities, self–reporting is the most cost–effective method to ensure CIRM is aware of difficulties in complying with the law. These provisions are based on the National Institutes of Health Grants Policy Statement (Dec. 2003) and thus provides consistency with institutions familiar with federal policy and practice in this area.

<u>SECTION 100060 — SCRO MEMBERSHIP AND</u> FUNCTION:

Purpose:

The purpose of this regulation is to describe the composition and functions of the designated SCRO committee. The purpose of the SCRO is to provide scientific and ethical review of CIRM–funded research consis-

tent with the requirements of Section 100070 and other applicable CIRM requirements.

Rationale:

This regulation is necessary to provide grantees guidance on the composition and function of the SCRO in overseeing stem cell research funded by the CIRM. The SCRO is a requirement embodied in section 100040. The membership, function and SCRO investigator functions are derived directly from recommendations contained in the National Academy of Sciences Guidelines. The regulation provides flexibility that allows multiple institutions to use the same SCRO to address resource or expertise realities. It is necessary to define the membership and functions to ensure efficient and consistent administration of grantee research.

100070—SCRO REVIEW AND NOTIFICATION:

Purpose:

- (a) This section states that CIRM—funded research involving derivation of covered stem cell lines or use of human oocytes or embryos in stem cell research may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (a)(3) of this regulation as a condition of granting its approval. This regulation identifies the criteria the investigator must address in the research proposal.
- (b) CIRM—funded research introducing covered stem cell lines into human or non—human animals at any state of embryonic, fetal, or postnatal development may not commence without SCRO committee review and approval in writing. This section identifies the elements the SCRO must consider in evaluating when to approve such research.
- (c) CIRM—funded purely in vitro research utilizing covered stem cell lines may not commence without written notification to the designated SCRO Committee. This section identifies the minimum contents of the notice.

Rationale:

- (a) This section is necessary to ensure consistency in administration of research involving stem cells. The requirements for SCRO approval for CIRM–funded derivation, the demonstration of expertise, documentation of compliance with necessary review, and documentation of how cell lines will be characterized are based on recommendations of the National Academy of Sciences. This section is necessary to ensure a consistent oversight process that will help ensure that research with human embryonic stem cells is conducted in a responsible and ethically sensitive manner.
- **(b)** This section is necessary to ensure that these requirements pertain to all cell lines used by CIRM-

funded researchers. The requirements to evaluate probably pattern of differentiation and document compliance with necessary review ensures consistent oversight process that will help ensure that research with human embryonic stem cells is conducted in a responsible and ethically sensitive manner. Likewise, these requirements are based on recommendations adopted by the National Academy of Sciences.

(c) This section is necessary to assure consistent oversight process that will help ensure that research with human embryonic stem cells is conducted in a responsible and ethically sensitive manner. This requirement is consistent with CIRM's grants administration policy and National Academy of Sciences Guidelines. The intent is to ensure that all CIRM—funded research is adequately tracked at the institution. The type of research covered in this section does not necessitate formal "scientific and ethical review" because it does not involve human subjects. None the less, it is critical for purposes of complete oversight that the SCRO be aware of research being performed at the institution. This provision requires a notification mechanism.

<u>SECTION 100080 — ACCEPTABLE RESEARCH</u> MATERIALS:

Purpose:

The purpose of this section is to require that all covered stem cell lines used in CIRM—funded research be acceptably derived. Each subdivision identifies particular criteria that meet the definition of "acceptably derived." Subdivisions (a) through (c) permit use of stem cells approved by the National Institutes of Health, deposited in the United Kingdom Stem Cell Bank or used or approved by a licensee of the United Kingdom Human Fertilization and Embryology Authority. Subdivision (d) permits use of cells derived in accordance with the Canadian Institutes of Health under applicable regimes.

(e) This section identifies 5 conditions on the use of cells; 1) requiring informed consent of donors; 2) assurance the donors have not been compensated for their donation; 3) prohibiting purchase or sale of gametes, embryos, somatic cells or human tissue, except as provided in subdivision (e)(2) of this regulation (permitting reimbursement for permissible expenses); 4) that donation of materials was overseen by an IRB or IRB equivalent; that donors who consented to donate stored materials were not reimbursed for the cost of storage prior to the decision to donate.

Rational:

This section is necessary to fulfill the requirement that CIRM establish the appropriate regulatory standards and oversight bodies for research and facilities development, pursuant to the State Constitution. Health and Safety Code section 125290.35, subdivision (b), re-

quires CIRM establish standards for obtaining informed consent of research donors and participants, standards prohibiting compensation to research donors (but allow reimbursement for expenses), and limits payments for the purchase of stem cells or stem cell lines (except for reasonable payments for expenses associated with the handling of such materials).

The entities identified in subdivisions (a) through (d) meet standards established by the National Institutes of Health or otherwise meet standards identified by the Standards Working Group. As such, these subdivisions are necessary to address the issue of stem cells lines created prior to enactment of Proposition 71 and define the permissible lines for use in CIRM—funded research. This allows needed flexibility and ensures availability of acceptable stem cell lines for CIRM—funded research ensuring proper standards are adhered to.

Subdivision (e)(1) is necessary to ensure compliance with Health and Safety Code requirement that donors have provided informed and voluntary consent. This also is considered a fundamental protection under federal law (see Code of Federal Regulations, Title 45, Part 46) and National Academy of Sciences Guidelines, number 3.1.

Subdivision (e)(2), prohibiting donors from receiving valuable consideration, is required by Health and Safety Code section 125290.35, subdivision (b)(3), as a standard prohibiting compensation. This term, as defined above in Section 100020, subdivision (h), provides clarity by defining permissible expenses that may be reimbursed.

Subdivision (e)(3) is necessary to ensure that all persons, in addition to donors, to not receive valuable consideration for the purchase or sale of stem cells or other similar materials. This section implements Health and Safety Code section 125290.35, subdivision (b)(5), which does allow payments for removal, storage, processing, and other handling of stem cells.

Subdivision (e)(4) is necessary to ensure that material donation is overseen by an IRB or its equivalent. This is consistent with federal law, which makes the IRB responsible for ensuring fundamental protection under federal law and is a major recommendation of the National Academy Guidelines for stem cell research. Moreover, this provision is consistent with California Health and Safety Code section 125300, which requires IRB oversight of various aspects of donation of gametes, embryos and tissue.

Subdivision (e)(5), prohibiting compensation for storage costs for those who elect to donate stored blastocysts, is necessary to ensure compliance with the statutory prohibition of compensation and ensures that payment of such costs is not an inducement to donate. This provision is consistent with National Academy Guide-

lines, Number 3.4, subdivision (a), governing stem cell research.

SECTION 100090: ADDITIONAL REQUIREMENTS FOR CIRM-FUNDED RESEARCH:

Purpose:

This section identifies further requirements with which the SCRO must affirm compliance when CIRM funds are used to derive new human stem cell lines. These requirements are in addition to those required by Section 100080, subdivision (e).

- (a) The SCRO must confirm that donors of material have given voluntary and informed consent (as set forth in Section 100900).
- (b) Where obtaining oocytes is required for derivation, the SCRO must confirm that the following conditions have been met that the donor's fertility treatment has not been compromised; the funded institution has agreed to assume the cost of medical care required as a result of the donation for research; that the physician attending the donor and the principal investigator are not the same person (unless approved by the IRB); and that the physician performing oocyte retrieval not have a financial interest in the outcome of the research.

Rationale:

- (a) Health and Safety Code Section 125290.35, subdivision (b)(1), requires CIRM establish standards for obtaining the informed consent of research donors, patients or participants. This section is necessary to ensure that documentation by the proper oversight authority has ensured that the requirements of Section 100100 have been met.
- (b) These requirements are based on public input and National Academy Guidelines to establish protections for prospective donors necessary to ensure donors are not exploited. Ensuring the attending physician and principal investigator are not the same individual is designed to erect a barrier against competing interests in oocyte donation. This ensures that oocyte donation will not come at the expense of the best interests of the patient, medically, and is consistent with National Academy Guidelines (3.5). Ensuring the physician does not have a financial interest in the research outcome will help to minimize potential undue influence in oocyte donation circumstances.

<u>SECTION 100100 — INFORMED CONSENT</u> REQUIREMENTS:

Purpose:

(a). Subdivision (a) states that all CIRM—funded research on human subjects is subject to Federal and state law governing human subject research and informed consent. Existing law provides that state requirements contained in California Health and Safety Code Section

- 24173 regarding informed consent do not apply to certain research within an institution that holds federal assurance and that has obtained informed consent in the method and manner required under federal law.
- **(b).** This subdivision prohibits conduct of human subject research that violates documented donor preferences with regard to use of donated materials. To ensure fully informed disclosure the subparts of this subdivision identifies the information that must be disclosed to donors.
- (c). ResearcheRs must provide donors with the opportunity to describe permissible uses for donated materials. The regulation also permits researchers to use only materials from donors who have agreed to all future used for donated materials.
- (d). This subdivision identifies additional disclosure requirements that must be made by researchers to donors that apply in the context of human egg donation. These requirements are intended to ensure documented informed consent.
- (e). For CIRM—funded research involving the donation of embryos for stem cell research, the informed consent process shall include a statement that embryos will be destroyed in the process of deriving embryonic stem cells.
- (f). For CIRM-funded research involving the donation of the umbilical cord, cord blood or the placenta, consent shall be obtained from each known legal parent, guardian or progenitor. Informed consent shall include a statement as to whether the donated cells may be available for autologous treatment in the future.
- (g). For CIRM—funded research involving the donation of somatic cells for SCNT, informed consent shall include a statement as to whether the donated calls may be available for autologous treatment in the future.

Rationale:

California Health and Safety Code Section 125290.35, subdivision (b)(1), requires CIRM to adopt standards for informed consent of donors. The following provisions are considered necessary to implement the requirement of this statute in a manner reflecting the best practices of existing research and draws on federal guidelines with which institutions are familiar.

(a). This subdivision is necessary to describe the parameters of existing law and identify the circumstances under which this regulation does not apply. California Health and Safety Code Section 24178, subdivision (a), states that Section 24173 shall not apply to any person who is conducting a medical experiment as an investigator within an institution that holds an assurance with the United States Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal regulations and who obtains informed consent

in the method and manner required by those regula-

(b). This subdivision applies several rules. The rule providing that research not violate the preferences of donors is necessary to ensure the integrity of the donor system that is integral to obtaining materials essential to stem cell research. This rule embodies National Academy Guidelines (3.6) that provide that donors could be offered the option of agreeing to some forms of human embryonic cell research but not others and that the consent process should fully explore whether donors have objections to any specific forms of research to ensure that their wishes are honored.

The informed consent requirements are consistent with existing the National Academy Guidelines and existing California regulations. A statement that cells may be kept for many years is already part of California Health and Safety Code section 125315, as well as part of NAG 3.6(f).

The National Academy Guidelines (3.6(d)) recommend that if the identities of donors are retained, the donor be informed as to whether he or she wishes to be contacted in the future to receive information obtained trough studies of the stem cell lines. This recommendation is embodied subdivision (b)(2).

Through feedback and work of the Standards Working Group, it was determined that it was necessary to emphasize to donors that future uses may exist for research that may be unknown at the time of the donation (subdivision (b)(3)). This is necessary to ensure that donors are informed that research topics and subject areas are evolving and that their material may, with their consent, be used for such studies if the donor chooses.

Subdivision (b)(5) requires a statement that cells may be transplanted into humans or animals. This statement is necessary in light of existing research practices, is considered a subject that might be relevant to some donors and for which consent should be obtained or awareness established. This is consistent with National Academy Guidelines recommendations (3.6(g)).

Subdivision (b)(6) clarifies that no direct medical obtains to the donor by virtue of the donation, except in obvious cases where the donation is autologous in nature, for the benefit of the donor. This clarification seeks to avoid potential confusion surrounding donation and is consistent with concerns identified by the National Academy Guidelines (3.6)(i)).

Subdivision (b)(7) clarifies that donations are made without restriction on who may be the recipient of the transplants of the cells derived, except in the obvious case where the donor is the intended recipient. This clarification ensures avoidance of potential confusion surrounding donation and is consistent with concerns identified by the National Academy Guidelines (3.6(b)).

Subdivision (b)(8) seeks to assure that patients do not feel coerced into donation materials and assures that neither consenting to nor refusing to participate in donation will have any effect on quality of any future care provided to the potential donor. This clarification ensures avoidance of potential confusion surrounding donation and is consistent with concerns identified by the National Academy Guidelines (3.6(k)).

Subdivision (b)(9) is necessary to make the potential donor aware of the fact that study involving the donor's materials may have a commercial potential but that the donor will not received financial or any other benefits from any future commercial development. This clarification ensures avoidance of potential confusion surrounding donation and is consistent with concerns identified by the National Academy Guidelines (3.6(h)). This already is a required element comprising informed consent in the context of materials used obtained during fertility treatment (California Health and Safety Code Section 125315, subdivision (c)(5)).

(c). Subdivision (c) embodies National Academy Guidelines recommendations (3.6(h)) that the consent process should fully explore whether donors have objections to any specific forms of research to ensure that their wishes are honored. The Standards Working Group has determined that this element in the regulation is necessary to ensure that such objections have the opportunity for expression.

(d). Subdivision (d) — The Standards Working Group has identified oocyte donation issues as particularly complex and controversial and thus requiring specials standards. Particular risks associated with egg donation have been identified and comprise the substantive disclosure requirement in (d)(1) of the regulation. This is consistent with federal regulation on point in the context of federal funding (Title 45 CFR, Part 46).

Existing law (Health and Safety Code Section 24173, subdivision (c)(11)) requires that any material financial stake or interest that the investigator or research institution has in the outcome of the medical experiment be disclosed. Accordingly, this requirements is embodied in the context of oocyte donation under subdivision (d)(2) of this regulation to ensure potential donors are aware of any potential for conflicts of interest on behalf of researchers,

Subdivision (d)(3) provides for necessary time to ensure that the donor fully understands what the donor is consenting to and is provided time upon which to reflect on the information given and to weigh the factors present in the decision. Similarly, subdivision (d)(4) is necessary to ensure that there is actual comprehension of the factors involved in the donation and that the consent being given or withheld is truly informed. This subdivision provides flexibility for researchers to determine

that the donor understands fundamental and essential aspects of the research.

- (e). This subdivision requires clarification with the donor that there is an understanding that embryos will be destroyed in the process of deriving human embryonic stem cells. This clarification ensures avoidance of potential confusion surrounding donation and is consistent with concerns identified by the National Academy Guidelines (3.6(j)).
- (f). This subdivision is seen as a necessary extension of National Academy Guidelines to address cord blood and placenta. This clarification is necessary to ensure avoidance of potential confusion surrounding donation of these materials and identifies from whom the consent shall be derived. This is necessary to ensure consistent application of the law and ensure the proper consent is derived from necessary individuals.
- (g). This subdivision is necessary to ensure that donors are aware as to whether donated cells for SCNT may be available for autologous treatment in the future. This clarification ensures avoidance of potential confusion surrounding donation and is consistent with concerns identified by the National Academy Guidelines (3.6(i)).

<u>SECTION 100110</u> — FAIRNESS AND DIVERSITY IN RESEARCH:

Purpose:

The purpose of this section is to require compliance with the California Health Research Fairness Act, and Inclusion of Women and Minorities in Clinical Research Act.

Rationale:

The California Health Research Fairness Act, California Health and Safety Code, Sections 439.900–439.906, and Inclusion of Women and Minorities in Clinical Research Act, Health and Safety Code, Sections 100237–100239, state California policy with respect to research fairness and the inclusion of women and minorities in clinical research funded by the State of California. The Standards Working Group identified fairness and inclusion as a priority and composed this section to ensure that existing state policies and law regarding research clearly applies in the context of CIRM–funded research.

SECTION 100120—RECORD KEEPING:

Purpose:

This section requires grantee institutions to maintain described records that concern CIRM—funded research activities. The subdivisions of this section require a research registry contain necessary documentation of CIRM-funded stem cell research conducted by the institution; pertinent review or notification requirements as required in Section 120600 of these regulations; the methods utilized to characterize and screen the materials for safety; the conditions under which the materials have been maintained and stored, where applicable; record of all gametes, somatic cells, embryos or products of SCNT that have been donated, created or used so as to determine the provenance and disposition of such materials. The section also requires a cross—reference for additional documentation that may be required by CIRM.

Rationale:

This regulation is necessary to ensure compliance with requirements imposed on the CIRM to track the use of CIRM funds and to ensure compliance with applicable statutes and regulations. National Academy Guidelines (6.1) state that institutions should required documentation of the provenance of all human embryonic stem cell lines, whether the cells were imported into the institution or generated locally. Notice to the institution should include evidence of IRB-approval of the procurement process, evidence of and adherence to basic ethical and legal principles of procurement, as indicated in the recommendation. In the case of lines imported from another institution, it is recommended that documentation that these criteria were met at the time of derivation will suffice. This section ensures the integrity of the donation process is assured and that future use of particular stem cell lines and materials can comply with necessary provenance and derivation requirements.

SECTION 100130 — MATERIALS SHARING:

Purpose:

The purpose of this section is to require that stem cell lines and biomedical materials developed with CIRM funding at academic, commercial research and development organizations be broadly disseminated. CIRM—funded research institutions must comply with any CIRM—Intellectual Property regulations intended to ensure data and materials sharing.

Rationale:

This regulation is necessary to cross reference CIRM regulations pertaining to inventions and other intellectual property that may pertain to grantees. This regulation adds nothing substantive beyond that which may be required from time to time by CIRM Intellectual Property regulations but ensures that grantees are aware that such particular requirements may be applicable.

TITLE 20. PUBLIC UTILITIES COMMISSION

PUBLIC UTILITIES AND ENERGY DIVISION 1 PUBLIC UTILITIES COMMISSION

NOTICE OF PROPOSED REGULATORY ACTION

The California Public Utilities Commission (Commission) proposes to amend regulations described below after considering all comments, objections, or recommendations regarding the proposal.

At a duly noticed regularly scheduled meeting not earlier than May 11, 2006, at 10:00 a.m., in the Commission Auditorium, 505 Van Ness Avenue, San Francisco, the Commission will consider a proposal to amend the Rules of Practice and Procedure set forth in Division 1, Chapter 1 of Title 20 of the California Code of Regulations. The proposed amended regulations will clarify, simplify and shorten the rules, and make them more accessible to practitioners before the Commission; repeal rules that have been rendered obsolete by changes in statute or practice; and enact substantive changes to implement statutory changes and changes in Commission practice, and to codify interim rules currently in effect under Commission resolutions or general orders.

AUTHORITY TO ADOPT RULES

Article XII, Section 2 of the California Constitution and Section 1701 of the Public Utilities Code authorize the Commission to adopt Rules of Practice and Procedure.

INFORMATIVE DIGEST

The California Public Utilities Commission proposes amendment to its Rules of Practice and Procedure.

We propose to amendments to Rules of Practice and Procedure in order to clarify and shorten them. For the most part, the proposed amendments (1) delete rules that have been rendered obsolete by changes in statute or practice, (2) delete redundancies, (3) edit rules to reflect and formalize existing Commission practices, and (4) simplify the language and organization of the rules.

Some of the proposed amendments would also enact substantive changes to codify changes in statute and Commission practice, and interim rules currently in effect under Commission resolutions. These changes include:

- Implement Stat. 2005, Ch. 591 by modifying the rules regarding public review and comment on alternate decisions;
- Extend applicability of the code of ethics to persons who offer testimony at hearing;
- Eliminate scoping ruling requirement in proceedings with no hearings;
- Apply ex parte requirements of underlying proceeding to applications for rehearing and petitions for modification;
- Require requests for *ex parte* "equal time" meetings to be made within 15 days of being notified of the initial individual meeting;
- Require electronic service of notices of ex parte communications in some circumstances;
- Eliminate the Shortened Procedure Tariff Docket for the filing of applications to increase common carrier rates;
- Modify rules to clarify the information required in applications concerning railroad and light-rail transit crossings;
- Codify the Commission's interim law and motion discovery procedures; and
- Correct erroneous description of circumstances constituting an "unforeseen emergency situation."

AVAILABILITY OF STATEMENT OF REASONS AND PROPOSED TEXT

The Commission's Order Instituting Rulemaking for the proposed rule amendments is available on the Commission's web site, http://www.cpuc.ca.gov/PUBLISHED/FINAL DECISION/53891.htm. The order includes a more detailed initial statement of the reasons for the rule amendments. Appendices A and C to the order set forth the complete text of the proposed rule amendments.

COMMENTS AND INQUIRIES

Any interested person may submit written comments concerning the proposed rule amendments. The written comment period closes at 5:00 p.m. on April 24, 2006. All comments must be filed (by submitting an original and four copies) at the Commission's Docket Office by that time. Send one additional copy of comments to the following contact person:

Hallie Yacknin
Administrative Law Judge
California Public Utilities Commission
Division of Administrative Law Judges
505 Van Ness Avenue
San Francisco, CA 94102
Telephone: (415) 703–1675
e-mail: hsy@cpuc.ca.gov

Inquiries concerning the substance of the proposed amendment, requests for copies of the text for the proposed amendment, or other questions should be directed to ALJ Yacknin at the above street or e-mail address or telephone number. The entire rulemaking file (Docket No. R.06–02–011) is also available for inspection and copying at the Commission's Central Files, Room 2002, at the above street address.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

Following the comment period, the Commission may adopt the proposed rule amendments substantially as described in this notice. If modifications are made that are sufficiently related to the originally proposed text, the modified text, with the changes clearly indicated, will be made available to the public for at least 15 days prior to the date on which the Commission adopts the rule amendments. Requests for copies of any modified rule amendments should be sent to the attention of ALJ Yacknin at either of the addresses indicated above. The Commission will accept written comments on the modified regulations for 15 days after the date on which the modifications are made.

TITLE 21. DEPARTMENT OF TRANSPORTATION

NOTICE OF PROPOSED RULEMAKING ACTION

The Department of Transportation (Department) proposes to adopt as permanent regulations new and amended regulations that establish the procedures for selection of private architectural and engineering firms. The Department will consider all comments, objections, and recommendations specifically directed at the proposed action or the procedures followed before the Department adopts the proposed rulemaking action.

NOTICE OF PUBLIC HEARING¹

Notice is hereby given that a public hearing on the proposed rulemaking action will be held:

Date: May 1, 2006

Time: 9:00 a.m. - 12:00 p.m.

Location: 1120 N Street, Sacramento, CA,

Room 1450¹

At the hearing, any interested person or authorized representative may present oral or written statements, arguments or contentions relevant to the rulemaking a

¹ If you need reasonable accommodations due to disability, please contact Maria Angel at (916) 654–2630.

ction described in the Informative Digest. The Department may impose reasonable limits on oral presentations. Persons making oral presentations at the hearing are asked to provide a written copy of their testimony at the conclusion of their remarks.

Written comments other than those presented at the hearing may be submitted to the Department as given below.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department.

The written comment period closes at 5:00 p.m. on May 1, 2006. The Department will consider only comments received at the following address by that time. Submit comments to:

KATHY SWANGER
Department of Transportation
Division of Procurement and Contracts

1727 30th Street Sacramento, CA 95816

Comments that are not more than 10 pages will be accepted by fax at (916) 227–6155. A fax transmission must be completed by the deadline given above.

Comments may also be submitted electronically to Kathy Swanger at kathy_swanger@dot.ca.gov by the deadline given above.

AUTHORITY AND REFERENCE

Authority Citation: The proposed regulations and the proposed amended regulations are authorized by Government Code sections 4526, 4529.10, 4529.14, California Constitution, Article XXII sections 1 and 2 and the Public Contract Code section 6106.

Reference Citation: The particular code sections implemented, interpreted, or made specific by these proposed new and amended regulations are Government Code sections 4525–4529.5, 4529.10–4529.20, 87100, California Constitution, Article XXII sections 1 and 2 and Public Resources Code section 21065.

INFORMATIVE DIGEST: Summary of Existing Laws and Effects of Proposed Rulemaking

Background and History: Before November 8, 2000

Under California constitutional law, State civil service employees must perform services provided by State agencies generally. These services cover a broad range of activities — such as clerical support, building maintenance and security. In some cases, however, the State may contract with private firms to obtain services.

Such contracting is allowed, for example, if services needed by the State are (1) of a temporary nature, (2) not available within the civil service, or (3) of a highly specialized or technical nature. Unlike the State, local governments are not subject to constitutional restrictions on contracting for services.

The State and local governments frequently contract with private firms for construction—related services, which include architectural, engineering, and environmental impact studies. State and local governments enter into these contracts through a competitive process of advertising for the service, selecting the firm determined to be best qualified, and negotiating a contract with that firm. However, neither the State nor most local government entities use a bidding process for these services. By comparison, bidding generally is used to acquire goods and for construction of projects.

Existing Law: Effective November 8, 2000

On November 7, 2000, the California voters approved an initiative measure (Proposition 35) that resulted in a constitutional amendment (see Article XXII, sections 1 and 2) and the enactment of certain statutory laws (see Government Code, sections 4529.10–4529.20).

The amended State Constitution allows the State and local governments to contract with qualified private entities for architectural and engineering services for all phases of a public works project. Thus, government agencies could decide to contract out for these specific services in any case, rather than just on an exception basis.

The new enacted statutory laws:

- Define the term "architectural and engineering services" to include all architectural, landscape architectural, environmental, engineering, land surveying, and construction project management services; and
- Require architectural and engineering services to be obtained through a fair, competitive selection process that avoids conflicts of interest.

Effect of Proposed Rulemaking

The proposed regulations reflect the constitutional amendments and statute enactment from November 8, 2000, which presently are not represented in the Department's existing regulations that were last updated in 1982.

INFORMATIVE DIGEST-POLICY STATEMENT OVERVIEW

The objective of the proposed regulations and proposed amended regulations is to improve the Department of Transportation (Department) internal procedures for contracting for architectural and engineering services.

The current Department regulations were last amended/updated in 1982 and do not reflect the passage of Proposition 35 (an initiative measure effective since November 8, 2000). Proposition 35 eliminated certain restrictions on the State to allow contracting with private qualified entities for engineering and architectural services in all phases of public works projects.

The scope of definitions in the proposed regulations has been broadened and also clarified.

Government Code section 4526 authorizes the Department to adopt regulations for the aforementioned purposes.

The regulations in this rulemaking do not differ substantially from existing comparable federal statute or regulations.

COMPARABLE FEDERAL REGULATION OR STATUTE

The proposed regulations do not differ substantially from existing comparable federal statute or regulations. The proposed regulations avoid duplication and conflict with federal statutes and federal regulations.

LOCAL MANDATE DETERMINATION

These regulations do not create a local mandate. The Department has determined that the proposed rulemaking does not impose a mandate on local agencies or schools, or a mandate that is required under part 7 (beginning with section 17500), Division 4, Title 2, of the Government Code.

DISCLOSURES/ESTIMATE OF ECONOMIC AND FISCAL IMPACT

Fiscal Impact on Local Agencies or School Districts: There will be no fiscal impact on local governments because they generally can now contract for architectural and engineering services. These regulations do not impose any cost on a local agency or school district which is required to be reimbursed pursuant to government Code sections 17500–17630, nor do they impose any non–discretionary cost or saving on a local agency.

Fiscal Impact on State Government: Unknown fiscal impact on State spending for architectural and engineering services and construction project delivery. Actual impact will depend on how the State uses the con-

tracting flexibility granted by these regulations. These regulations will not result in any cost or savings in federal funding to the State.

Initial Determination Regarding Impact on Housing Costs: The Department has made an initial determination and is not aware of any effect the proposed action will have on housing costs.

Initial Determination Regarding Economic Impact on Business: The Department has made an initial determination that the proposed action will not have a significant, statewide, adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. (These regulations increase the business opportunities since they are designed to select private firms that offer services to the Department.)

Assessment of Effect on Jobs and Businesses: Adoption of these regulations will not: (1) create or eliminate jobs within California; (2) create new businesses or eliminate existing businesses within California; or (3) affect the expansion of businesses currently doing business within California.

Cost Impact on Representative Person or Business: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Determination Regarding Effect on Small Business: The Department has made an initial determination and is not aware of any adverse effect on small businesses. Small businesses with access to electronic publication tools will have more of an opportunity to compete for services under these regulations.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5, subdivision (a)(13), the Department must determine that no reasonable alternative which is considered or which has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Inquiries concerning the proposed administrative action may be directed to:

Kathy Swanger, Contract Analyst Department of Transportation Division of Procurement and Contracts 1727 30th Street, Sacramento, CA 95816

Telephone: (916) 227–6094

Fax: (916) 227-6155

Kathy_Swanger@dot.ca.gov

The backup contact person for these inquiries is:

Megan Rettke, Contract Officer Department of Transportation Division of Procurement and Contracts 1727 30th Street, Sacramento, CA 95816

Telephone: (916) 227-6083

Fax: (916) 227–6155 Megan_Rettke@dot.ca.gov

Questions on the substance of the proposed regulations may be directed to Kathy Swanger.

Please direct requests for copies of the proposed text (the "express terms") of the regulations, the initial statement of reasons, the modified text of the regulations, if any, or other information upon which the rulemaking is based to Kathy Swanger at the above address.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

The Department will have the entire rulemaking file available for public inspection and copying throughout the rulemaking process at its office at the above address. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, the Initial Statement of Reasons and the Economic and Fiscal Impact statement (STD Form 399). Copies may be obtained by contacting Kathy Swanger at the address or phone number listed above.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After holding the hearing and considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes substantive modifications which are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Department adopts the regulations as revised.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, copies of the Final Statement of Reasons may be obtained by contacting Kathy Swanger

at the above address and will be made available through the Department website at http://caltrans-opac.ca.gov/ aeinfo.htm.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations can be accessed through the Department website at http://caltrans-opac.ca.gov/aeinfo.htm.

TITLE 22. EMPLOYMENT TRAINING PANEL

NOTICE OF PROPOSED RULEMAKING

NOTICE IS HEREBY GIVEN that the Employment Training Panel (Panel) proposes a series of regulatory actions, primarily regarding Multiple Employer Contracts for New Hire Training. Other actions are proposed to clarify general contracting procedures.

Specifically, the Panel proposes to adopt new Sections 4400(ll), 4400(mm) and 4406; amend existing Section 4440.3; and repeal existing Sections 4440(l) and 4406 in Title 22 of the California Code of Regulations. These proposed actions are discussed further here and in the Initial Statement of Reasons (ISOR). The ISOR and the Express Text of the proposed amendment are accessible through the *What's New* link on the Home Page of the ETP website (www.etp.ca.gov).

AUTHORITY AND REFERENCE

The Panel's rulemaking authority is set forth at Section 10205(m) of the Unemployment Insurance (UI) Code. The proposed regulatory action would implement, interpret and make specific Sections 10200, 10205, 10206, 10209 and 10210 of the UI Code.

INFORMATIVE DIGEST

Adopt Section 4400(11)

Currently, there is no statutory or regulatory definition of the term "contractor" even though that term is used by the Panel in reference to the reimbursement of training costs. New Section 4400(ll) would define "Contractor" as the entity responsible for satisfying the duties and obligations set forth in an ETP Agreement in order to earn the reimbursement amount approved by the Panel. It would specify the types of entities that may contract with the Panel consistent with UI Code Section 10205(c), and establish that this may be in the form of a

Multiple Employer Contract or Single Employer Contract.

Adopt Section 4400(mm)

Currently, there is no statutory or regulatory definition of a Multiple Employer Contract (MEC) even though that term is used by the Panel in reference to the reimbursement of training costs under an ETP Agreement with certain entities. New Section 4400(mm) would define a MEC as a group of employers, training agency or other eligible Contractor operating on the behalf of multiple participating employers.

Adopt Section 4401.1

Currently, the enabling law requires In–Kind Contributions from employers and contractors at UI Code Sections 10200, 10205 and 10206. There is also a definition of In–Kind Contributions at T.22, C.C.R. Section 4400(1). In addition, the Panel adopted an Employer Contributions policy in May 2001 that addresses the same subject. Proposed Section 4401.1 would implement the policy, and combine it with the definition at Section 4400(1) which would be repealed.

This proposed regulation would also implement the statutory requirements. Specifically, UI Code Section 10206(b) requires In–Kind Contributions by a contractor or employer. The Panel has always applied this requirement to employers for workers who are undergoing "retraining" to improve existing job skills. In that instance, the employer is known and is often the actual contractor. The employer's contributions to the cost of training can be identified and set forth as a representation in the ETP Agreement.

In recent years, under its Employer Contributions policy, the Panel has also applied the requirement for In–Kind Contribution to prospective participating employers identified by a MEC contractor under a new hire training project designed to provide job skills to unemployed workers. That type of employer does not hire the trainees until they had completed the training project. As a practical matter, that type of employer cannot be accurately identified in time for the Panel's consideration of a MEC funding proposal, which is when the contractor makes a commitment to pay In–Kind Contributions.

Even though a prospective participating employer may be identified by the contractor in a MEC funding proposal, that employer does not make a binding commitment to hire trainees and cannot be held accountable for In–Kind Contributions. This proposed regulation would not alter the fact that MEC contractors must still commit to paying In–Kind Contributions, the same as employer contractors. Likewise, payment of said contributions requirement would still apply to actual (not prospective) participating employers identified by the contractor under a MEC.

This new regulation would also specify the type of costs that may be included in determining the amount of In–Kind Contributions consistent with the Panel's Employer Contributions policy.

Adopt Section 4406

It has been the Panel's experience that the cost-pertrainee for new hire training of unemployed workers, which is typically delivered under a MEC, greatly exceeds the average cost-per-trainee for retraining employed workers. At present, there is no cap on the cost of new hire training.

New Section 4406 would cap the cost—per—trainee for new hire training under a MEC, at the average cost—per—trainee paid during the prior Fiscal Year for all completed new hire training projects. For example, the ETP Annual Report for 2004–05 shows \$4,740 as the average cost—per—trainee for new hire training based on data from the last year. This new regulation would provide for waiver of the cap on a case—by—case basis if post—retention earnings are set at an amount that is proportionately higher than the ETP new—hire minimum earnings in effect at the time of Panel approval.

This new regulation would also require MEC contractors to demonstrate a recruitment plan for trainees and participating employers, and establish an employer advisory board.

Under UI Code Section 10205(e), MEC contractors must identify employers that have provided "reasonable assurance" of employment for the new hire trainees. At present, this requirement is implemented through the Panel's Multiple Employer Contracts policy, which requires evidence of employer demand for new hire training. The Panel accepts a list of prospective participating employers as such evidence, but it has determined that this list is too speculative and that a qualified advisory board would be more likely to provide reasonable assurance of employment.

The employer advisory board must have prospective participating employers as members. It must provide guidance on training needs in specific or specialized occupations, and on workforce shortages in said occupations. The advisory board must also provide an ongoing evaluation of the training curriculum.

Note: Existing Section 4406, on a new-hire training program for promotional activities that is now lapsed, would be repealed.

Amend Section 4440.3

Existing Section 4440.3 establishes that: (a) the term of a contract for ETP funding cannot begin prior to Panel approval; (b) a contractor may begin training prior to contract execution if so authorized; (b)(1) there is a 7–day waiting period between Panel approval of the "final contract" and the start–of–training, with a possible waiver; (b)(2) a contractor must acknowledge the au-

thorization at (b) in writing; and, (b)(3) reimbursement depends on contract execution and compliance.

This amendment would clarify subsection (a) and (b) and eliminate the requirement for written authorization at subsection (b)(2). That requirement is unnecessary because the contracting parties can set a term retroactive to the date of signature as an aspect of contract law.

This amendment would also eliminate the other requirements at subsection (b), for the same reason. That is, the 7-day time period at (b)(1) is unnecessary because contracting parties can negotiate the term which then establishes the date for start-of-training. If this 7-day time period is removed, the acknowledgement at (b)(2) would become unnecessary. Likewise, the reimbursement provision at (b)(3) are aspects of contract law that govern without the need for a regulation.

Repeal Section 4400(1)

The definition of In–Kind Contributions would be repealed because it would be incorporated into proposed Section 4401.1.

Repeal Section 4406

The requirements for the Panel's review and payment of promotional activities by new hire training contractors would be repealed because that program is no longer in operation.

No documents would be incorporated—by—reference in any of these proposed regulatory actions.

FISCAL DISCLOSURES

The Panel has made the following initial determinations regarding fiscal disclosures required by Section 11346.2 of the Government Code:

A. Fiscal Impact. The Panel has made an initial determination that the proposed regulatory action does not impose costs or savings requiring reimbursement under Section 17500 *et seq.* of the Government Code. Furthermore, this action does not impose non–discretionary costs or savings to any local agency; nor does it impact federal funding for the State.

The Panel has made an initial determination that the proposed regulatory action does not impose costs or savings to any State agency pursuant to Section 11346.1(b) or 11346.5(a)(6) of the Government Code. Furthermore, there are no fiscal impact disclosures required by State Administrative Manual Sections 6600–6670.

B. Cost Impacts. The Panel is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. The same determination applies to housing costs. This action would clarify the Panel's standards for reviewing and funding training proposals. Thus, the costs incurred in submitting such a proposal should be reduced, if anything.

C. Adverse Impact on Business. The Panel has made an initial determination that the proposed regulatory action does not have any significant, statewide adverse economic impact directly affecting business, including the ability to compete. Indeed, the overall purpose of the Panel's program is to enhance the ability of California businesses to meet the challenge of competition from other states.

<u>D. Effect on Small Business</u>. The Panel has determined that the proposed regulatory action does not affect small businesses unless they seek training funds. Since this action would clarify and simplify the Panel's standards for reviewing and funding training proposals, this would be a positive effect.

E. Effect on Jobs and Business Expansion. The Panel has made an initial determination that the proposed regulatory action would not create or eliminate jobs in California. Nor would it create new businesses or eliminate existing businesses in California. The Panel has made an initial determination that this action would not directly affect the expansion of businesses currently operating in California.

Nevertheless, the overall intent and purpose of the ETP program is to foster job creation and the retention of high—wage, high—skilled jobs that are threatened by out—of—state competition. (U.I. Code Section 10200(a).) The Panel must give funding priority to projects that would train new employees of firms locating or expanding in the state; train displaced workers, and develop workers with skills that prepare them for the challenges of a high performance workplace of the future. (U.I. Code Section 10200(b).) Thus, the Panel has made an initial determination that the proposed regulatory action may encourage the retention of jobs and businesses in California, insofar as they would enhance the Panel's ability to implement the purpose of the ETP program.

<u>F. Imposed Mandate</u>. The Panel has made an initial determination that the proposed regulatory action does not impose a mandate on local agencies or school districts.

REASONABLE ALTERNATIVES

The Panel has made an initial determination that there is no reasonable alternative to the proposed regulatory action that would be more effective in carrying out its purpose, or would be as effective and less burdensome to affected private parties. Interested persons are welcome to identify reasonable alternatives during the written comment period.

WRITTEN COMMENT PERIOD

A 45–day written comment period has been established beginning on March, 17, 2006 and ending at 5:00 p.m. on April 24, 2006. Any interested person or his or her authorized representative may present written comments on the proposed action within that time period. Comments should be sent to:

Maureen Reilly, Acting General Counsel Employment Training Panel, Legal Unit 1100 "J" Street, Fourth Floor Sacramento, CA 95814 Telephone: (916) 327–5470 E-Mail: mreilly@etp.ca.gov

FAX: (916) 327–5268

PUBLIC HEARING

A public hearing will not be held unless one is requested by an interested person, or his or her authorized representative. The request must be submitted in writing to Ms. Reilly at the address shown above no later than 5:00 p.m. at least 15 calendar days before the written comment period ends. The request should identify the specific regulatory action for which the hearing is requested.

MODIFICATIONS

Modifications to the text of the proposed regulatory action may be made after the public comment period. If so, they will be posted on the ETP Website at www.etp.ca.gov. They will also be available upon request to Ms. Reilly. Said modifications will be open to public comment for at least 15 days before their adoption, as noticed on the ETP Website.

AVAILABILITY OF DOCUMENTS

The Panel has prepared an Initial Statement of Reasons for the proposed action, and has compiled all information on which this action was based. This statement, along with the express text of the proposed action and the written information on which it was based, are available for inspection at the address shown above. Any inquiries should be directed to Ms. Reilly.

The Panel will prepare a Final Statement of Reasons at the conclusion of the public comment period. This final statement and the information on which it was based will also be available for inspection at the written comment address shown above.

This Notice of Proposed Rulemaking is posted on the ETP Website at www.etp.ca.gov. The Initial Statement of Reasons and the express text of the proposed action are also posted on the ETP Website. When the Final

Statement of Reasons is prepared, it will be posted on the ETP Website.

CONTACT PERSONS

Requests for copies of the express text of the proposed regulatory action, along with the modified text (if any) and the Initial Statement of Reasons, should be directed to Ms. Reilly using the contact information shown above. In addition, the "rulemaking file" of written information on which the proposed action is based is available for inspection through Ms. Reilly. In the event Ms. Reilly is unavailable, inquiries regarding the proposed regulatory action should be directed through the Legal Unit Secretary, Terza Rodoni, at the same address and/or phone number listed above, or by email at trodoni@etp.ca.gov.

GENERAL PUBLIC INTEREST

FISH AND GAME COMMISSION

TITLE 14. FISH AND GAME COMMISSION

Notice of Date Change for Public Hearing On Proposed Regulatory Action

In a notice of proposed regulatory action published in the California Regulatory Notice Register 2006, No. 7–Z, on February 17, 2006, the Fish and Game Commission proposed to amend Sections 360, 361, 362, 363 and 364, Title 14, CCR, regarding mammal regulations. The date of the hearing relevant to this action has been changed from May 5, 2006 to Thursday, May 4, 2006, at 8:30 a.m. The location remains the same at the North Tahoe Conference Center, 5318 North Tahoe Blvd., in Kings Beach, CA. Written comments must be received no later than May 4, 2006, at the hearing in Kings Beach. For additional information, please refer to the notice published on February 17, 2006.

FISH AND GAME COMMISSION

TITLE 14. FISH AND GAME COMMISSION

Notice of Date Change for Public Hearing On Proposed Regulatory Action

In a notice of proposed regulatory action published in the California Regulatory Notice Register 2006, No. 7–Z, on February 17, 2006, the Fish and Game Commission proposed to amend Section 679, Title 14, CCR, regarding wildlife rehabilitation. The date of the hearing relevant to this action has been changed from May 5, 2006 to Thursday, May 4, 2006, at 8:30 a.m. The location remains the same at the North Tahoe Conference Center, 5318 North Tahoe Blvd., in Kings Beach, CA. Written comments must be received no later than May 4, 2006, at the hearing in Kings Beach. For additional information, please refer to the notice published on February 17, 2006.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Notice to Interested Parties March 17, 2006

Announcement of a Public Comment Period and Public Workshop

Public Comments on the Child-specific Toxicity Criteria for Endosulfan and Lead for Use in Assessing Health Risks at Existing and Proposed School Sites

The Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency is making available for review and comment the two draft reports, "Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code Section 901(g): Proposed Child-Specific Reference Dose (chRD) for School Site Risk Assessment, Endosulfan" and "Development of Health Criteria for School Site Risk Assessment Pursuant To Health And Safety Code Section 901(g): Proposed Child-Specific Benchmark Blood Lead Concentration For School Site Risk Assessment." Health and Safety Code (HSC), Section 901(g) requires the Office of Environmental Health Hazard Assessment (OEHHA), in consultation with the appropriate entities within the California Environmental Protection Agency, to identify those chemical contaminants commonly found at school sites and determined by OEHHA to be of greatest concern based on child-specific physiological sensitivities. HSC 901(g) also requires OEHHA to annually evaluate and publish, as appropriate, numerical health guidance values (HGVs) for those chemical contaminants until the contaminants identified have been exhausted. The child-specific criteria

for endosulfan and lead are being considered at this time.

This public review and comment period follows the requirements set forth in Health and Safety Code Section 57003 for receiving public input. A public workshop will be held from 10 a.m. to 12 p.m. on April 12, 2006, in the Sierra Hearing Room on the second floor of the Joe Serna (Cal/EPA headquarters) Building, 1001 I Street, Sacramento, California, to discuss the proposed child–specific criteria on endosulfan and lead. Because there will be no official transcript of the meeting, we recommend that oral comments also be submitted in writing. OEHHA requests comments on these draft reports be delivered to OEHHA by 5:00 p.m. on May 1, 2006. Comments received by that date will be considered in revision of the documents.

If you would like to receive further information on this announcement or have questions, please contact our office at (916) 324–2829 or the address below. Written requests or comments should be addressed to:

Mr. Leon Surgeon Integrated Risk Assessment Section Office of Environmental Health Hazard Assessment P.O. Box 4010 1001 I Street Sacramento, California 95812–4010

FAX: (916) 322-9705

E-mail: lsurgeon@oehha.ca.gov

SUMMARY OF REGULATORY ACTIONS

REGULATIONS FILED WITH SECRETARY OF STATE

This Summary of Regulatory Actions lists regulations filed with the Secretary of State on the dates indicated. Copies of the regulations may be obtained by contacting the agency or from the Secretary of State, Archives, 1020 O Street, Sacramento, CA, 95814, (916) 653–7715. Please have the agency name and the date filed (see below) when making a request.

BOARD OF VOCATIONAL NURSING AND PSYCHIATRIC TECHNICIANS

Consumer Complaint Disclosure

This action adopts the Board's consumer complaint disclosure policy for vocational nursing (VN) and psychiatric technicians (PT).

Title 16

California Code of Regulations ADOPT: 2524.1, 2579.11

Filed 03/02/06

Effective 04/01/06

Agency Contact: Angelina Martin (916) 263–7859

DEPARTMENT OF FISH AND GAME

Tank Vessel Escort Program for Los Angeles/Long Beach Harbors

Under existing section 851.23 of title 14, all escort tugs in the Los Angeles/Long Beach Harbor used for escorting vessels must have their static bollard pull measured and certified at least once every three years. Existing subsection (a)(6)(A)1. provides for an extension to the board pull re–test date for good cause for up to one year from the date the bollard pull test certificate expires. This emergency regulatory action would amend subsection (a)(6)(A)1. to lengthen the extension period to up to two years from the date the bollard pull test certificate expires.

Title 14

California Code of Regulations

AMEND: 851.23 Filed 03/01/06 Effective 03/01/06

Agency Contact: Joy Lavin–Jones (916) 327–0910

DEPARTMENT OF FOOD AND AGRICULTURE

This emergency action expands and redefines of the list of host plants and plant parts that are hosts or potential carriers of oak mortality disease based upon the actions of the Animal and Plant Health Inspection Service (APHIS) on February 10, 2006, listing these plants and plant parts as hosts or potential carriers.

Title 3

California Code of Regulations

AMEND: 3700(c) Filed 03/07/06 Effective 03/07/06

Agency Contact: Stephen Brown (916) 654–1017

DEPARTMENT OF FOOD AND AGRICULTURE Mediterranean Fruit Fly Interior Quarantine

In this Certificate of Compliance filing, the Department of Food and Agriculture amends a regulation pertaining to the "Mediterranean Fruit Fly Interior Quarantine" to expand the quarantine area in the Rancho Cucamonga area of San Bernardino County.

Title 3

California Code of Regulations

AMEND: 3406(b) Filed 03/01/06 Effective 03/01/06

Agency Contact: Stephen Brown (916) 654–1017

EMERGENCY MEDICAL SERVICES AUTHORITY EMT. Irrapulations

EMT-I regulations

Emergency Medical Services Authority proposes amendments to four EMT–I regulations to clarify and make consistent sections govern training, continuing education, refresher course, course challenge, certification, re–certification, and reciprocity requirements for EMT–Is.

Title 22

California Code of Regulations

AMEND: 100058, 100066, 100078, 100079

Filed 03/07/06 Effective 04/06/06

Agency Contact: Sean Trask (916) 322–4336

FISH AND GAME COMMISSION Lure

This regulatory action creates definitions for terms repeatedly used in Division 1, Subdivision 1 of CCR Title 14, but that were not previously defined. The terms being defined are "lure," "non–buoyant lure," and "weight." This action also clarifies, without changing, the boundary for the Sacramento–San Joaquin River Delta.

Title 14

California Code of Regulations

ADOPT: 1.60, 1.61, 1.93

AMEND: 1.71 Filed 03/02/06 Effective 04/01/06

Agency Contact: Sherrie Koell (915) 653–4899

STATE PERSONNEL BOARD

Whistleblower Retaliation Complaint

This regulatory action revises provisions governing whistleblower retaliation complaints. The existing process involves an initial documentary review process after which the Executive Officer may recommend that the case be sent to a full evidentiary hearing. This regulatory action replaces the initial documentary review step with an informal hearing process. This regulatory action is submitted as exempt from the Administrative Procedure Act pursuant to section 18211 of the Government Code and is submitted to the Office of Administrative Law for filing with the Secretary of State and publication in the California Code of Regulations pursuant to section 18214 of the Government Code.

Title 2

California Code of Regulations

AMEND: 56, 56.1, 56.2, 56.3, 56.4, 56.5, 56.6, 56.7,

56.8

Filed 03/08/06

Effective 03/08/06 Agency Contact: Elizabeth Montoya

(916) 654-0842

CCR CHANGES FILED WITH THE SECRETARY OF STATE WITHIN OCTOBER 05, 2005 TO MARCH 08, 2006

All regulatory actions filed by OAL during this period are listed below by California Code of Regulation's titles, then by date filed with the Secretary of State, with the Manual of Policies and Procedures changes adopted by the Department of Social Services listed last. For further information on a particular file, contact the person listed in the Summary of Regulatory Actions section of the Notice Register published on the first Friday more than nine days after the date filed.

Title 1

I IIIC I				
12/29/05	AMEND: 1038			
Title 2				
03/08/06	AMEND: 5	66, 56.1, 56.2, 56.3	, 56.4, 56.5,	
	56.6, 56.7, 56.8			
02/28/06	AMEND: 5	57.1, 57.2, 57.3, 57.	4	
02/21/06	ADOPT: 18371			
02/21/06	REPEAL: 2550, 2551, 2552, 2553, 2554,			
	2555, 2556	, , , , , , , , , , , , , , , , , , , ,	,	
02/21/06	AMEND: 2	2320(a)(2)		
02/21/06	ADOPT: 18	3361.10		
02/16/06	AMEND: I	Div. 8, Ch. 58, Sec. 3	54700	
01/30/06	AMEND: I	Div. 8, Ch. 103, Sec	. 59150	
01/24/06	REPEAL:	649.23, 649.25	6, 649.26,	
	649.27			
01/23/06	AMEND: 1	8351		
01/20/06	AMEND: 1897			
01/17/06	AMEND: Div. 8, Ch. 64, Sec. 55300			
01/17/06	ADOPT: 560 REPEAL: 560			
12/29/05	AMEND: 18329.5, 18701, 18751			
12/21/05	AMEND: 599.960, 599.961			
12/20/05	AMEND: 18700, 18707, 18708			
12/12/05		20108, 20108.1,	,	
		20108.18,		
		20108.30,		
		20108.37,		
	20108.40,	20108.45,	20108.50,	
	20108.51,		20108.60,	
		20108.70, 20108.75	5, 20108.80	
11/16/05	AMEND: 1			
11/07/05	ADOPT: 1859.300, 1859.301, 1859.302,			
	1859.310,			
	1859.313,			
		1859.317,	1859.318,	
	1859.319,	1859.320,	1859.321,	
	1050 202	1050 202	0.50 000 1	

1859.322,

1859.323,

1859.323.1,

	1859.323.2, 1859.324, 1859.325, 1859.326, 1859.327, 1859.328,	12/05/05 12/05/05	AMEND: 1977 REPEAL: 1959.5, 1959.6, 1959.7,
11/07/05	AMEND: 20107	12/00/00	1959.8, 1976.5, 1976.7
10/31/05	AMEND: 1859.2, 1859.81, 1866	11/28/05	ADOPT: 7075, 7076, 7077, 7078, 7079,
10/27/05	AMEND: 1859.2, 1859.51, 1859.104.3,	11/20/03	7079, 7080, 7081, 7082, 7083, 7084,
10,27,05	1859.147, 1859.202, 1866, Form SAB		7085, 7086, 7087, 7088, 7089, 7090,
	50–01		7091, 7092, 7093, 7094, 7095, 7096,
10/24/05	ADOPT: 1859.23 AMEND: 1859.2,		7091, 7092, 7093, 7094, 7093, 7096, 7097, 7098, 7099 REPEAL: 7000, 7001,
	1859.122, 1859.123, 1859.123.1		7003, 7004, 7005, 7006, 7007, 7008,
10/18/05	ADOPT: 18732.5		7009, 7010, 7011, 7012, 7013, 7013.
10/11/05	ADOPT: 18117, 18772	11/28/05	ADOPT: 503, 512, 515, 516, 517, 518,
10/11/05	AMEND: 18450.4	11/20/03	519, 523, 524 AMEND: 500, 501, 502,
10/11/05	AMEND: 18401, 18427.1, 18700,		519, 523, 524 AMEND: 500, 501, 502, 510, 513, 514, 520, 552, 530, 531, 533
	18705, 18707.9, 18730, 18750		REPEAL: 521
10/06/05	ADOPT: 18735.5	11/23/05	AMEND: 4083
Title 3		11/23/03	
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